

James E. Cecchi
Donald A. Ecklund
CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.
5 Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700

Edward Braniff
James Morris
WEITZ & LUXENBERG, P.C.
700 Broadway
New York, New York 10003
(212) 558-5500

*Attorneys for Plaintiff Deloris M. Zessin,
Marilyn Young and Susan Johnson*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: FOSAMAX (ALENDRONATE SODIUM)
PRODUCTS LIABILITY LITIGATION

MDL No. 2243
Master Docket No. 08-08 (JAP)(LHG)
Civil Action No. 11-cv-3918 (JAP)(LHG)
Civil Action No. 11-cv-3225 (JAP)(LHG)
Civil Action No. 11-cv-5301 (JAP)(LHG)

THIS DOCUMENT RELATES TO:

Document Filed Electronically

*Zessin v. Merck Sharp & Dohme Corp., f/k/a Merck
& Co., Inc.,
Civil Action No.: 11-cv-3918 (JAP)(LHG)*

*Young v. Merck Sharp & Dohme Corp., f/k/a Merck
& Co., Inc.,
Civil Action No.: 11-cv-3225 (JAP)(LHG)*

*Johnson v. Merck Sharp & Dohme Corp., f/k/a
Merck & Co., Inc.,
Civil Action No.: 11-cv-5301 (JAP)(LHG)*

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANT'S MOTION TO STRIKE DR. ROBERT MAKUCH AND
EXCLUDE HIS TESTIMONY AT TRIAL**

TABLE OF CONTENTS

Table of Authorities	iii, iv
I. Introduction	1
II. Argument	2
A. Merck’s Motion Should Be Denied Because Dr. Makuch’s Report was Timely Under CMO 4(A)	2
B. Merck’s Motion Should Be Denied for Failure to Comply with Local Civil Rule 37.1 for the District of New Jersey	4
C. Merck Does Not Satisfy the Prerequisites for the Severe Remedy That it Seeks	6
D. Plaintiff’s Disclosure of Dr. Makuch is Harmless Under All Authorities	7
E. Even If the Law Allowed Sanctions in this Case, The Facts of the Case Do Not Warrant Them.....	9
III. Conclusion	10

TABLE OF AUTHORITIES

Cases:

<i>ABB Air Preheater, Inc v. Regenerative Envtl. Equip. Co.</i> , 167 F.R.D. 668 (D.N.J. 1996).....	8
<i>Acorda Therapeutics Inc. v. Apotex Inc.</i> , Civil Action No. 07-4937 (GEB-MCA), 2011 WL 52521 (D.N.J. Jan 6, 2011)	4
<i>Bowers v. Nat’l Collegiate Athletic Ass’n</i> , Civil Action No. 97-2600 (SMO), 1998 WL 35180779, (D.N.J. Sept. 17, 1998)	5
<i>Exxon Corp. v. Halcon Shipping</i> , 156 F.R.D. 589 (D.N.J. 1994).....	9
<i>Fitz, Inc. v. Ralph Wilson Plastics Co.</i> , 174 F.R.D. 587 (D.N.J. 1997).....	1
<i>Huertas v. City of Camden</i> , Civil Action No. 06-4686, 2008 U.S. Dist. LEXIS 90219, (D.N.J. Nov. 6, 2008).....	5
<i>In re Paoli R.R. Yard PCB Litig.</i> , 35 F.3d 717 (3d Cir. 1994).....	8
<i>Meyers v. Pennypack Woods Home Ownership Ass’n</i> , 559 F.2d 894 (3d Cir. 1977).....	4
<i>Network Appliance, Inc., v. Bluearc Corp.</i> , No. C 03-5665 MHO, 2005 U.S. Dist. LEXIS 16726, (N.D. Cal. June 27, 2005)	7
<i>Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div.</i> , 60 F.3d 153 (3d Cir. 1995)	4, 8
<i>Nicholas v. Pa. State Univ.</i> , 227 F.3d 133 (3d Cir. 2000).....	8
<i>RLA Mktg, Inc. v. WHAM-O, Inc.</i> , Civil Action No. 04-3442 (HAA), 2007 U.S. Dist. LEXIS 16629, (D.N.J. Mar. 5, 2007).....	5

<i>Tech. Dev. Co. LTD, v. Onischenko</i> , Civil Action No. 05-4282 (MLC), 2009 U.S. Dist. LEXIS 93034, (D.N.J. Oct. 5, 2009).....	5
--	---

Other Authorities:

D.N.J. Local Civ. Rule 37.1	1, 4, 5
Fed. R. Civ. P. 26.....	2, 3, 4, 8
Fed. R. Civ. P. 37.....	4, 6, 7, 8

Case Management Orders:

CMO 4.	3, 4
CMO 4(A).....	2, 3, 4

I. INTRODUCTION

Plaintiffs, Deloris M. Zessin, Marilyn Young, and Susan Johnson respectfully submit this memorandum of law in opposition to the motion of Defendant Merck Sharp & Dohme Corp. (“Merck”) to strike Dr. Robert Makuch’s expert report and preclude him from testifying at trial.¹ As this Court is aware, trial is set to commence in the *Zessin* matter in January 2014. On April 1, 2013, Plaintiff timely served Dr. Robert Makuch’s report on counsel for Merck, approximately ten months before the January 2014 trial date, and within the time to serve expert disclosures in the *Zessin* matter.

The disclosure of Dr. Makuch’s report and his testimony at trial will not prejudice Merck. Indeed, in late-April, after serving Dr. Makuch’s report, Plaintiff offered to produce Dr. Makuch for his deposition within 30 days – a date that would have likely occurred *before* the return of this motion and certainly months before trial – and to allow Merck to serve an appropriate rebuttal report to respond to his opinions, which would have remedied any resulting prejudice. *See Fitz, Inc. v. Ralph Wilson Plastics Co.*, 174 F.R.D. 587, 591 (D.N.J. 1997) (finding that prejudice from late disclosure of an expert may be remedied by permitting deposition and allowing supplemental briefing). Merck refused this offer.

Further, notwithstanding the parties’ efforts throughout this litigation to attempt to amicably resolve discovery disputes in accordance with Local Civil Rule 37.1 for the District of New Jersey, Merck filed this motion without even attempting to resolve this dispute. In this District, however, before filing a motion seeking to strike an expert report or other evidence, the movant must first try to meet and confer. Merck has not only made no efforts to meet and

¹ Because Merck filed its motion to strike in the remaining initial bellwether trials (*Zessin*, *Young*, and *Johnson*), Plaintiffs are filing this opposition on behalf of all three Plaintiffs. However, the discovery deadlines at issue only pertain to Plaintiff Deloris Zessin, and therefore, reference to Plaintiff throughout this brief refers to Plaintiff Deloris Zessin.

confer, it has rejected Plaintiff's invitations to do so twice since the filing of its premature motion.

For all the foregoing reasons, Merck's motion to strike should be denied.

II. ARGUMENT

A. Merck's Motion Should be Denied Because Dr. Makuch's Report was Timely Under CMO 4(A).

In this case, Plaintiff Deloris Zessin's submission of her Rule 26(a)(2) expert disclosure was timely made. Merck argues that the general causation expert in *Zessin* is different from the one identified in *Glynn* and thus cannot be used in the *Zessin* case. However, the expert discovery provided in the *Glynn* trial was specific to *Glynn*. In the *Glynn* case, expert disclosure was made pursuant to procedures put in place by this Court pursuant to Case Management Order ("CMO") 4(A). Specifically, CMO 4(A), provides specific and different discovery deadlines for the *Glynn* and *Zessin* matters. This CMO sets forth the disclosure deadlines in the *Glynn* matter at page 2, paragraph 4, under the clearly labeled heading "4. *Glynn* Pretrial Schedule." Pursuant to this schedule, the parties in *Glynn* were required to complete expert discovery by January 11, 2013. The provisions that fall under the *Glynn* heading are specific to the *Glynn* case, and no other case. There is no mention of the MDL or any denoted MDL expert deadlines set forth under the *Glynn* heading.

The *Zessin* case has its own italicized heading and following paragraph which sets out a timetable for Rule 26(a)(2) disclosure and expert depositions. Although Defendant argues that Dr. Makuch's disclosure is prejudicial, Merck recently disclosed experts in the *Zessin* case who are being clearly being offered for the purpose of their generic opinions.² Plaintiff followed the

² Merck's attempts to exclude Dr. Makuch's expert report on the basis that his opinions are

very same procedures in the *Zessin* case when she filed her Rule 26(a)(2) disclosure. Pursuant to the CMO 4 procedures, Plaintiff identified the *Zessin* expert disclosure as being related to the **individual** case of *Deloris Zessin*.³ See **Exhibit B**, Plaintiff *Deloris Zessin's* Rule 26(a)(2)

pertinent only to general causation and thus are somehow prejudicial to its defenses in the *Zessin* case and/or violate its inappropriate and erroneous interpretation of CMO 4, are unfounded in light of the substance of its own expert reports served in the *Zessin* case. Among the nine experts disclosed in the *Zessin* case, there are two experts, Drs. Socrates Papapoulos and Gary Friedlaender, who were not previously disclosed in the *Glynn* case. Presumably, following the faulty logic presented in Merck's motion to exclude the testimony of Dr. Robert Makuch, these newly-disclosed Merck experts are to offer case-specific opinions about Mrs. Zessin.

The substance of these two reports, however, are patently those of general causation experts based on the length and breadth devoted to their general causation discussion and opinions, and the questionable relevance of many of these opinions to Mrs. Zessin's case. For example, Dr. Friedlaender offers a 36-page report in which there is no discussion of Mrs. Zessin until page 27. Similarly, Dr. Papapoulos's report, spanning 88 pages in length, does not discuss the *Zessin* case until page 68, a case-specific evaluation that spans only 11 pages before turning to a critique of Dr. Mechrefe's report.

Moreover, the scope of the general causation opinions offered ranges widely, with many topics having little or nothing at all to do with the Zessin case. For example, pages 7-11 of Dr. Papapoulos's report discusses at length a variety of diseases of the skeleton such as Paget's disease, malignancy-associated bone disease, osteomalacia, ectopic calcification and ossification, and osteopetrosis, none of which are relevant to the *Zessin* case. Dr. Papapoulos devotes pages 11-18 of his report to a discussion of bisphosphonates generally. On pages 25-28, Dr. Papapoulos devotes an entire section to the effects of bisphosphonates on the incidence of vertebral fractures, yet another condition wholly irrelevant to Mrs. Zessin's medical history. He further devotes many pages to long-term effects of bisphosphonates, length of treatment of osteoporosis with bisphosphonates, and summarizes five general causation questions that provide the premise for the next 23 pages of his report. Though these opinions very well may be relevant and well-founded for a general caution expert report, they have questionable and limited relevance to Mrs. Zessin's case-specific analysis.

If Merck indeed intended, for the deadlines in the *Glynn* section of the CMO 4(A) to apply to *Zessin* general causation experts, it is puzzling that Merck has designated two experts in *Zessin* whose opinions focus largely on general causation.

³ It is also notable that in the *Glynn* case, the expert reports of Drs. Charles Cornell and Michael J. Klein were exchanged with the Defendant and labeled as relating to the individual case of *Bernandette Glynn and Richard Glynn*. The labeling of these reports was done pursuant to the requirements and procedures set forth in CMO 4, page 4 paragraph 2, which requires papers and documents related to **individual** cases to be labeled in that manner. Likewise, Defendant's *Daubert* motion in the *Glynn* case to preclude the testimony of Drs. Charles Cornell and Michael J. Klein was also labeled as relating to the **individual** case of *Bernandette Glynn and Richard Glynn*. See **Exhibit A**, Excerpted Expert Reports of Drs. Charles Cornell and Michael J. Klein, dated 10/15/2012, annexed to the Declaration of James E. Cecchi. Clearly Merck's *Daubert* motion did not seek to preclude these expert witnesses testimony as to all cases in the MDL,

disclosure, served 4/1/2013, annexed to the Declaration of James E. Cecchi. Accordingly, the expert disclosure in the *Zessin* case was timely served under CMO 4(A) and Defendants motion should be denied.

B. Merck's Motion Should Be Denied for Failure to Comply with Local Civil Rule 37.1 for the District of New Jersey.

Even if the factual underpinnings of Merck's motion supported its claimed relief, Merck's effort to strike Dr. Makuch should fail because it is contrary to Rule 37 of the Federal Rules of Civil Procedure and Local Civ. Rule 37.1. Merck's reliance on Rule 26 instead of Rule 37 is inappropriate. *See Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div.*, 60 F.3d 153, 156 (3d Cir. 1995) (recognizing that Rule 37 "is designed to provide inducement for disclosure of Rule 26(a) material"). In this instance, both the parties' discovery dispute and the authority to strike Dr. Makuch's report and exclude his testimony are governed by Rule 37 and Local Civ. Rule 37.1. Merck offers no factual or legal basis for application of Rule 26 in connection with the relief that it seeks or authority that would excuse its violation of Rule 37 and Local Civ. Rule 37.1.⁴

otherwise it would have followed the procedures as set forth in CMO 4 page 4 paragraph 2.

⁴ In deciding whether to strike a late expert disclosure under Rule 26 and Rule 37, in this Circuit, courts consider: "(1) the prejudice or surprise to the party against whom the evidence is to be presented; (2) the ability of that party to cure the prejudice; (3) the extent to which the waiver of the schedule would disrupt the orderly and efficient trial of the case; and (4) bad faith or willfulness in failing to comply with the court's order." *Acorda Therapeutics Inc. v. Apotex Inc.*, Civil Action No. 07-4937 (GEB-MCA), 2011 WL 52521, at *1 (D.N.J. Jan. 6, 2011) (citing *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1977)). Each factor supports denial of Merck's motion.

The Court should deny Merck's motion to compel for failing to comply with Local Civ. Rule 37.1, which states:

Counsel shall confer to resolve any discovery dispute. Any such dispute not resolved shall be presented by telephone conference call or letter to the Magistrate Judge. This presentation shall precede any formal motion.

Here, Merck violated the letter and spirit of the rule by failing to meet and confer. Additionally, Merck did not present the discovery dispute to the Court *via* telephone conference call or letter. Having failed to do so, Merck is simply not entitled to the relief it seeks because the "motion itself is defective on its face." *Tech. Dev. Co. LTD, v. Onischenko*, Civil Action No. 05-4282 (MLC), 2009 U.S. Dist. LEXIS 93034, at *1, *6-7 (D.N.J. Oct. 5, 2009); *see also Huertas v. City of Camden*, Civil Action No. 06-4676, 2008 U.S. Dist. LEXIS 90219, at *1, *19-20 (D.N.J. Nov. 6, 2008) (denying sanctions for failure to meet and confer in good faith); *Bowers v. Nat'l Collegiate Athletic Ass'n*, Civil Action No. 97-2600 (SMO), 1998 WL 35180779, at *1, *2, (D.N.J. Sept. 17, 1998) (admonishing counsel for failure to follow the Local Rules before filing motion for leave to serve additional interrogatories); *see also RLA Mktg, Inc. v. WHAM-O, Inc.*, Civil Action No. 04-3442 (HAA), 2007 U.S. Dist. LEXIS 16629, at *1 (D.N.J. Mar. 5, 2007) (recognizing that failure to adhere to the procedure set forth in Local Civ. Rule 37.1 may require Court's involvement where meet and confer process may have resolved the dispute).

Merck also failed to comply with Local Civ. Rule 37.1(b)(1) by failing to include an affidavit certifying that they conferred "with the opposing party in a good faith effort to resolve by agreement the issues raised by the motion without the intervention of the Court and that the parties have been unable to reach agreement." *See* Local Civ. Rule 37.1(b)(1). Instead, Merck rushed to the Court with its premature motion before it even informed Plaintiff that it disagreed with the propriety of the report. Accordingly, the Court should deny Merck's motion

for failure to follow the local rules.

C. Merck Does Not Satisfy the Prerequisites for the Severe Remedy That It Seeks.

The express requirements of Rule 37, which provides the authority for imposing the drastic relief that Merck seeks, requires a showing that Plaintiff failed to meet her initial or supplemental disclosure obligations and that such failure was not “substantially justified or is harmless.” Merck does not – and cannot – make such a showing. Even if Merck could satisfy its Rule 37(c) burden of showing that Plaintiff’s disclosure of Dr. Makuch was untimely, the production was justified. The scope and breadth of the case, information that discovery continues to reveal, and insights gained from the trial in *Glynn* have necessarily impacted Plaintiff’s case. Plaintiff did not intentionally withhold any relevant reports or other evidence, waiting to spring them on Merck at or just before trial. Indeed, Plaintiff has already offered to produce Dr. Makuch for deposition and has offered to work out a schedule within which Merck could serve a supplemental report that addresses his opinions. Merck rejected this proposal. There is no bad faith on Plaintiff’s part and no support for the sanctions Merck seeks. Regardless, and as Plaintiff has always intended, she will produce Dr. Makuch for his deposition and will disclose any and all materials that support his opinions long before trial – and indeed, has offered to do so already.

D. Plaintiff's Disclosure of Dr. Makuch Is Harmless Under All Authorities.

Merck has failed to show some harm to justify precluding Plaintiff's from relying upon Dr. Makuch's report and testimony at trial. Merck's current objections to Dr. Makuch's report are especially remarkable as none of the case citations involved a similar circumstance and, in fact, most of them involved applications made pursuant to Rule 37. Moreover, none of Merck's case citations took place in a multi-district litigation setting where, as here, the expert report is timely under the disclosure deadlines in the individual bellwether case and, thus, provides adequate notice to Merck and ample time to conduct discovery of the opinions set forth in the report. No case allows a defendant to preclude an expert simply because the opinions will require that defendant engage in an analysis of the opinions – particularly over half a year before trial. Instead, Merck contends that it has been prejudiced because, in its view, the disclosure of Dr. Makuch is little more than an attempt to “jettison” Drs. Klein and Cornell or seek a “mulligan” from the Court. There is no factual support for either assertion. And not surprisingly, Merck provides no authority for the extraordinary relief that it now requests.

The uncontradicted and extensive case law holds that exclusion of evidence under Rule 37 is a severe remedy, only granted in extreme situations. “[O]n the menu of sanctions that a court may select from in applying Rule 37, preclusion of evidence is among the most severe; indeed, under certain circumstances, the imposition of preclusive sanctions may be tantamount to dismissal of a plaintiff's claims or entry of default judgment against a defendant.” *Network Appliance, Inc., v. Bluearc Corp.*, No. C 03-5665 MHO, 2005 U.S. Dist. LEXIS 16726, at *1, *9, *11-12 (N.D. Cal. June 27, 2005) (refusing Rule 37 request to exclude evidence based on assertions of untimely production). Where, as here, the moving party “has abundant time to depose [the expert] regarding the specifics of [his opinion],” there is “little in favor of

exclusion.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 792 (3d Cir. 1994).

Indeed, the only cases where expert testimony has been excluded under Rule 37 are where the precluded party springs new evidence or testimony on the other side at or just before trial. *See, e.g., Nicholas v. Pa. State Univ.*, 227 F.3d 133, 148 (3d Cir. 2000) (setting forth four factors to consider when considering whether to exclude expert testimony pursuant to Rules 26(a)(2) and 37(c)(1)); *Newman*, 60 F.3d at 156 (3d Cir. 1995) (observing that the district court should not exclude evidence or testimony if it would result in “fundamental unfairness in the trial of the case” or where there is prejudice, surprise or bad faith in not complying with the disclosure rules).

Even if Merck has acted in compliance with the rule, requests under Rule 37(c) for evidence preclusion, or even lesser sanctions, are regularly rejected on far more egregious facts than are alleged here. Indeed, “[t]he Third Circuit has, on several occasions, manifested a distinct aversion to the exclusion of important testimony absent evidence of extreme neglect or bad faith on the part of the proponent.” *ABB Air Preheater, Inc. v. Regenerative Envtl. Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996) (citing cases). Merck’s request, if granted, would be unprecedented. Contrary to the circumstances described above, in this case, Dr. Makuch was disclosed more than ten months before the trial is set to commence.⁵

Nothing Merck surmises about what it may need to do to respond to Dr. Makuch shows that it cannot and will not be ready to meet Plaintiff head-on at trial in January 2014. Plaintiff has agreed to produce Dr. Makuch for deposition so that Merck can probe the basis of his opinions and have also agreed to allow Merck to serve whatever supplemental report it believes

⁵ So long as Merck is not “surprised” at trial by any of Plaintiff’s experts’ opinions or evidence (which it will not be, because Plaintiff’s reports and testimony will be complete and clear and all evidence will have been produced), then it will have no future basis for a Rule 37(c)-based motion *in limine*.

is necessary to address his opinions. There is simply no surprise or bad faith. *See Exxon Corp v. Halcon Shipping*, 156 F.R.D. 589, 591 (D.N.J. 1994) (violations of scheduling orders coupled with unsatisfactory explanations may be characterized as bad faith). Plaintiff has offered a solution that will cure any theoretical prejudice and that will not disrupt the trial in January 2014.

Simply put, Dr. Makuch's report is timely and, even assuming *argumendo* that it was not, there is no prejudice to Merck. Rather, Plaintiff diligently endeavored to address Merck's concerns and rather than reflecting bad faith, Plaintiff requested to meet and confer with Merck to resolve these issues without involving the Court in compliance with the Federal Rules (an expression of Plaintiff's good faith), which Merck has rejected twice. The only thing that would interfere with the rightful decision of the case is barring Plaintiff from relying upon the opinions of a qualified expert disclosed several months before trial. In sum, Merck has come to the Court at the wrong time, and without making the necessary showing for the drastic, unprecedented relief it seeks.

E. Even If the Law Allowed Sanctions in this Case, the Facts of the Case Do Not Warrant Them.

In addition to having no support in case law, Merck's motion is undercut by the reality of this case's history. This record contains nothing remotely close to the facts necessary for preclusion. The actual record shows no prejudice to Merck – particularly on the expanded case schedule recently established by the Court. Regardless, Plaintiff disagrees that the Court's case management order somehow precluded the parties from disclosing different experts in the subsequent bellwether trials.

It is worth stepping back and considering what sanction Merck seeks by its motion. If a general causation expert who testified during *Glynn* was unable (for any reason) to render an

opinion or is unavailable to testify in *Zessin*, *Young*, or *Johnson* would those plaintiffs be precluded from relying upon another qualified expert? The preclusion that Merck seeks is draconian relief. It blocks any examination of Dr. Makuch's opinions, any examination of those opinions against the facts in this case (which differ from those in *Glynn*), and any effort to reach a just result. It hides the merits of Dr. Makuch's opinions for reasons that have nothing to do with those merits. The remarkable sanctions sought here cannot occur unless Merck meets all elements of the high standard required by the law on a record that is compelling. There is no basis for such sanctions here. Merck should depose Dr. Makuch and provide whatever supplemental report it believes is appropriate to respond to his opinions. Merck's Rule 37 motion (mischaracterized as a Rule 26 motion) must be denied.

III. CONCLUSION

This Court should deny Merck's motion to strike and should enter the proposed Order provided by Plaintiffs.

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.
Attorneys for Plaintiffs

BY: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: May 14, 2013

Of Counsel:
Edward Braniff
James Morris
WEITZ & LUXENBERG, P.C.
700 Broadway
New York, New York 10003
(212) 558-5500